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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,450	12/05/2003	Christina Khoo	7129-00	1031
23909 7590 07/09/2008 COLGATE-PALMOLIVE COMPANY 909 RIVER ROAD PISCATAWAY, NJ 08855				
EXAMINER				
FORD, ALLISON M				
ART UNIT		PAPER NUMBER		
1651				
MAIL DATE		DELIVERY MODE		
07/09/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/729,450

Applicant(s)

KHOO ET AL.

Examiner

ALLISON M. FORD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19 and 26-28 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 19 and 26-28 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Applicants' response of 4/3/2008 has been received and entered into the application file. Claim 19 has been amended, claims 26-28 have been added as new; claims 1-18 and 20-25 are cancelled. Claims 19 and 26-28 are pending in the application, all of which have been considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant case claim 27 defines the antioxidants as vitamin C, vitamin E, *precursors of vitamin C, precursors of vitamin E*, or combinations thereof. There is insufficient written description in the instant disclosure to adequately describe or define all precursors of vitamin C and of vitamin E which are to be included in the scope of this invention. While one of ordinary skill in the art recognizes vitamin C and vitamin E, and Applicants have specified tocopheryl acetate and sodium ascorbate (see pg 2, line 27-28), one would not immediately envisage all precursors of the vitamins which would be suitable for use in the claimed invention.

Applicants have not disclosed what functional characteristic of vitamin C and/or vitamin E the precursors must retain in order to be suitable for inclusion in the composition administered in the claims, and thus one cannot readily determine which precursors are included in the scope of the claimed genus.

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Furthermore, without disclosure of a specific function, there clearly is no disclosed correlation between function and structure, wherein such a correlation between structure and function is necessary to define a genus of chemical compounds, See *Enzo Biochem*, 323 F.3d at 964, 63 USPQ2d at 1613. An adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004). Therefore, it is not clear which precursors of vitamin C and/or vitamin E are to be included in the scope of the claim, and which are not.

Claim 28 is rejected under 35 U.S.C. 112, first paragraph, as failing to provide enablement for the full scope of the claim. The specification, while being enabling for treating diarrhea in a cat suffering from inflammatory bowel disease (IBD), by feeding said cat the diet disclosed in claim 19, wherein treating diarrhea includes *reducing* production of watery runny stool and soft unformed stool, does not reasonably provide enablement for *preventing* production of water runny stool and soft unformed stool in cats with IBD. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The

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factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all these factors are considered, a sufficient number are discussed below so as to create a prima facie case.

The claimed invention is directed to a method for preventing production of watery, runny stool and soft unformed stool in a cat suffering from IBD, by administering the diet recited in claim 19. Applicants' specification provides that when 12 test cats were fed diets containing glutamine and antioxidants (unknown amounts) 0% watery, runny stool or loose unformed stool was observed over a 2 week period, as compared to 7% watery, runny stool or loose unformed stool being observed over a 2 week period when the same cats were feed diets not containing glutamine or antioxidants.

While it is appreciated that Applicants have provided experimental evidence (Example 2), it is respectfully submitted that the test values presented are found insufficient to conclude that administration of a diet comprising glutamine, antioxidants, fermentable fibers and omega-3-fatty acids will completely *prevent* diarrhea (characterized as water, runny stools or loose unformed stools) in cats suffering from IBD. One of ordinary skill in the art will recognize that diarrhea can have a number of trigger factors, which extend beyond general intestinal cell health, which factors cannot be completely prevented (*e.g.* food poisoning, side-effects of medications, intestinal parasites, etc). The limited time period of the study (2 weeks) is insufficient to support the conclusion that diarrhea is completely *prevented* in the test animals, as prevention would involve prevention for the rest of the animal's life. In the absence of long term studies, during which the animals are exposed to a variety of conditions and factors which are known to trigger diarrhea, such a claim is found to be unsupported. Rather, it appears the claims should be

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limited to a method of ameliorating diarrhea symptoms in a cat with IBD (which is currently the subject matter of claim 19).

The burden of enabling the prevention of diarrhea, characterized by watery, runny stools or loose, unformed stools, is much greater than that of enabling the treatment of the same condition because it is more difficult to prevent the development or advancement of diarrhea or bowel irregularities than it is to simply ameliorate the symptoms associated with diarrhea and IBD. Since the present specification would not enable the skilled artisan to prevent diarrhea, a clear burden of undue experimentation would be placed upon the skilled artisan in order to practice this aspect of the invention.

As the discussion of a sufficient number of the above 8 factors establish that practicing the claimed method in the manner disclosed by Applicant would not imbue the skilled artisan with a reasonable expectation that the prevention of diarrhea could be achieved. In order to actually achieve prevention of this condition, it is clear from the discussion above that the skilled artisan could not rely on Applicant's disclosure as required by 35 U.S.C. §112, first paragraph. Given that the art fails to recognize and Applicant has failed to demonstrate that diarrhea could actually be prevented, the skilled artisan would be faced with the impermissible burden of undue experimentation in order to practice this embodiment of the claimed invention. Accordingly, claim 28 is deemed properly rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

In response to the rejection of record over Shields, Jr et al, in view of Wadsworth and Klimberg, Applicants have continued to argue that the primary references Shields, Jr et al is not applicable to the

instant method, as Shields, Jr et al is limited in discussion to dogs. Applicants further argue that one of ordinary skill in the art, in reading Shields, Jr et al would not be motivated to select the four currently claimed components for use in a diet for treating IBD in cats. Furthermore, Applicants argue that the secondary references, Wadsworth et al and Klimberg et al, fail to cure the deficiencies of the Shields, Jr et al reference, as there is no reason to combine the teachings.

Applicants' arguments remain unpersuasive for the reasons set forth in the Examiner's Answer (11/17/2006), and upheld by the BPAI decision (8/23/2007): Applicants are correct that Shields, Jr et al discloses a diet intended for administration to specific breeds of dogs. The diet formulation comprises a number of standard ingredients commonly found in pet foods (*e.g.* protein source such as chicken, fermentable fibers, and omega-3-fatty acids, antioxidants, etc). Shields, Jr et al continues to discuss the particular benefits of glutamine on intestinal health (the only component singled out for testing in the current examples). The teachings of Klimberg and Wadsworth further attest to the benefits of glutamine on intestinal health. Though Shields, Jr et al is directed to dogs, whereas the instant claims are now limited to cats, it remains that Wadsworth et al includes cats within their scope, and more generally that based on the similar digestive systems of cats and dogs (and rats, as discussed by Klimberg), all having a single stomach and small colon, thus one of ordinary skill in the art would have a reasonable expectation that the teachings of Shields, Jr et al, Wadsworth and Klimberg would be applicable to cats for the same purpose of managing diarrhea and gastrointestinal health. Therefore, because the references, when taken as a whole, suggest each of the claimed ingredients in the claimed amounts for administration as part of a diet for treatment of gastrointestinal distress, it would have been within the purview of the artisan of ordinary skill to administer the same composition to other mammals, particularly other mammals within the same Order (Carnivora), with a reasonable expectation of achieving the same results.

Furthermore, in response to Applicants' argument that there is no motivation to combine the primary references Shields, Jr et al with either of the secondary references, it is noted that in *KSR*

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International Co v Teleflex Inc 82 USPQ2d 1385 (US 2007) the Supreme Court stated that an explicit motivation to combine teachings of references is not necessary, "Rigid application of "teaching, suggestion, or motivation" test, under which patent claim is proved obvious only if prior art, nature of problem addressed by inventor, or knowledge of person having ordinary skill in art reveals some motivation or suggestion to combine prior art teachings, is inconsistent with expansive and flexible "functional approach" to resolution of obviousness issues" (See KSR at 1385). However, even though such an explicit motivation is no longer necessary, it is respectfully submitted that one of ordinary skill in the art, in reading Shields, Jr et al, would be motivated to look to other work in the same field (the field being diet compositions useful for treating gastrointestinal distress in mammals) for further discussion and teachings on the same topic, to produce an optimal diet composition for the purpose of treating gastrointestinal distress. Klimberg and Wadsworth et al each clearly fall into the same field of study, and as such, the artisan of ordinary skill would be motivated to review and combine their disclosures with that of Shields, Jr et al.

Therefore the arguments are not found persuasive to overcome the rejection of record. New rejections have been made over new claims 26 and 27.

In response to the rejection of record over Chandler et al, Applicants argue that the broad teachings of Chandler would not motivate one to arrive at the specific composition administered as part of the method of the instant claims.

Applicants' argument is are not found persuasive for the reasons set forth in the Examiner's Answer (11/17/2006), and upheld by the BPAI decision (8/23/2007): Though Chandler disclose a number of ingredients that can be fed to an animal with diminished gastrointestinal health, it remains that Chandler does specifically address each of the four claimed components as being beneficial. The motivation to combine each of these components, each individually taught by Chandler to be beneficial

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for treating gastrointestinal distress, comes from the well established principle that it is prima facie obvious to combine two or more compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. Regarding the specific concentrations of each claimed component, it is maintained that it would have been well within the purview of one of ordinary skill in the art to routinely optimize the concentrations of each component taught by Chandler to arrive at the composition used in the current claims. As stated previously, it is well established that differences in concentrations will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical or produces unexpected results. Again, while Applicants have shown inclusion of glutamine and antioxidants has an effect on stool formation in test animals, there is not evidence directed to the concentration of any one component, and no evidence that any particular concentration range is critical.

Therefore the arguments are not found persuasive to overcome the rejection of record. New rejections have been made over new claims 26 and 27.

Claims 19, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shields, Jr. et al (US Patent 6,156,355), in view of Wadsworth et al (US Patent 6,737,089) and Klimberg et al (*Arch Surg*, 1990), further in view of Taber's Cyclopedic Medical Dictionary (1997).

Shields, Jr. et al teach a dog food composition, 'The Herding Diet' which comprises fermentable fibers, in the amount of 4.0%; omega-3 fatty acids, in the amount of 0.2%; antioxidants; and glutamine (See Shields, Jr. et al, col. 9, ln 48-51; col. 11, ln 25-38 & 53-54; col. 12, ln 11-15; col. 23, ln 4-14 & 'Analysis'). The antioxidants included in the diet comprise tocopherols (vitamin E) and vitamin C (See Shields, Jr. et al, col. 5, ln 44-48). The 'Herding Diet' is specially formulated for dogs that are prone to

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chronic GI inflammation and diarrhea; it is designed to be fed to dogs as a means of controlling GI inflammation and diarrhea (See Shields, Jr. et al, col. 11, ln 18-28). Shields, Jr. et al teach that the glutamine is the primary source of fuel for the cells for the intestinal tract, and it is beneficial in stress situations (such as times of gastrointestinal stress), in particular it is beneficial to cells of the immune system of the intestinal tract (See Shields, Jr. et al, col. 12, ln 11-22); however, they do not disclose a precise amount of glutamine to include in the diet.

Regarding the amount of glutamine to be included in the diet composition, it is submitted that the claimed amount of glutamine would have been obvious to one of ordinary skill in the art, at the time the invention was made, based on the disclosure of Wadsworth et al and Klimberg et al. Wadsworth et al and Klimberg et al both provide similar teachings on the benefits of glutamine on intestinal health during times of gastrointestinal stress. It is submitted that diarrhea is a sign of diminished gastrointestinal health (See Taber's Cyclopedic Medical Dictionary, 1997). Wadsworth et al teach glutamine, 5-10% wt, as an additive to animals' diets, specifically dog and cat diets, can provide improved digestive system support (See Wadsworth et al, col. 7, ln 51-60 and col. 13, ln 34-49 (Example 4)). Klimberg et al teach adding glutamine, 3% wt, to diets of rats suffering gastrointestinal distress from abdominal radiation, resulted in diminished bloody diarrhea and reduced the incidence of bowel perforation (See Klimberg et al, Pg 1040, col. 2- Pg. 1041, col. 2). Therefore, it would therefore have been obvious to the person of ordinary skill in the art at the time the invention was made to use the amounts of glutamine specified by either Wadsworth et al or Klimberg et al (5-10% and 3%, respectively) in the diet disclosed by Shields, Jr. et al. Shields, Jr. et al already teach using glutamine in the 'Herding Diet' in order to treat stressed GI tracts, however because they do not teach a specific amount of glutamine, one of ordinary skill in the art would have been motivated to use the amounts of glutamine taught by Wadsworth et al and Klimberg et al. One would expect success because all three teach that glutamine treats stressed GI tracts by providing the essential fuel for intestinal immune cells.

Regarding the amount of antioxidants to be included in the diet composition, it is submitted that the claimed amount of antioxidants would have been obvious to one of ordinary skill in the art, at the time the invention was made, based on the disclosure of Wadsworth et al. While Shields, Jr. et al does teach the importance of antioxidants as scavengers of oxygen, and terminators of free radicals (col. 5, ln 65- col. 6, ln 11), they do not teach a specific amount of antioxidants present in the diet. However, Wadsworth et al also teach inclusion of vitamins and antioxidants, such as vitamins A and E, and disclose the desired amount as being from 0-10% by weight (See Wadsworth et al, col. 5, ln 24-42). However, any pharmaceutical amount would be appropriate for these diets. Excess vitamins are flushed from the system; therefore, it would be obvious to include any amount of antioxidants, within a pharmaceutically accepted range, with expectations of the benefits and without concern of over dosage. Therefore, though Shields, Jr et al is silent on the amount of antioxidants in their diet, it would have been obvious to include any amount within a pharmaceutical range, such as 0.1-3% by weight.

Finally, while it is noted that the composition of Shields, Jr et al, and its use in methods of managing gastrointestinal disorders, such as diarrhea, is limited to dogs, whereas Klimberg et al's experiments are conducted on rats, and Wadsworth et al's teachings are directed to both dogs and cats, it is submitted that the teachings of Klimberg et al and Wadsworth et al would have been recognized as extendable to dogs, as described by Shields, Jr et al. This statement is based on the fact that each of rats, cats and dogs are mammals having simple digestive tracts, and it is known that glutamine has similar beneficial effects on all three species (as disclosed by the individual references). For the same reasons it would be obvious to extend the results of Shields, Jr. et al, in view of Klimberg et al and Wadsworth et al, to cats; therefore, a diet of the same composition, including glutamine, fermentable fiber, omega-3 fatty acids, and antioxidants in the specified amounts, and use of such composition for the treatment of diarrhea, including diarrhea caused by intestinal bowel disease, would have been obvious for use in dogs as well as non-canine mammals, such as cats.

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 19, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler (*In Practice*, 2002).

Chandler teaches diets for dogs and cats for the treatment and control of gastrointestinal diseases, which result in symptoms such as diarrhea. Chandler et al teach that a diet, which includes fermentable fibers, omega-3 fatty acids, antioxidants, particularly water soluble vitamins C and B (See Pg. 531), and glutamine, can benefit an animal with a stressed gastrointestinal tract (See Chandler, Pg. 529, col. 2, and especially Pg. 533, col. 1). Chandler teaches a diet comprising these ingredients can be used as a treatment for gastrointestinal diseases (See Chandler, especially Pg. 533). It is noted that inflammatory bowel disease is a gastrointestinal disease that also results in symptoms such as diarrhea; therefore, despite the cause of the diarrhea, the diet recommended by Chandler would have the same effect on the symptoms of diarrhea.

Though Chandler is silent on the precise amounts of glutamine, fermentable fibers, omega-3 fatty acids, and antioxidants, it would have been obvious to a person of ordinary skill in the art to experiment with varying amounts, within pharmaceutical ranges, of each ingredient to optimize the treatment potential of the diet. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical or produces unexpected results. Where the general conditions of a claim are disclosed by the prior art it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Chandler teach that each specific ingredient plays an important role in maintaining and, in times of stress restoring gastrointestinal health (See Chandler, especially, Pg. 529, col. 1- Pg. 531, col. 1). A person of ordinary skill in the art would

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have been motivated to increase the amount of fermentable fiber, omega-3 fatty acids, and antioxidants, and to include glutamine in a diet for a dog or cat with GI tract problems because these ingredients are highly digestible, the fiber promotes fecal bulk, the omega-3 fatty acids help to decrease inflammation, antioxidants promote immune response, and need to be replaced during bouts of diarrhea due to being flushed out, and glutamine has been found to provide energy for enterocytes during times of stress, boosting immune ability and GI health (See Chandler, Pg. 529, col. 2- Pg. 533, col. 1). One would have expected success because Chandler describes a diet containing these ingredients as a means for treating GI problems, including diarrhea caused by inflammatory bowel disease (See Chandler, Pg. 529, col. 2- Pg. 533, col. 1). Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALLISON M. FORD whose telephone number is (571)272-2936. The examiner can normally be reached on 8:00-6 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651